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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,072	01/15/2002	Ralph M. Steinman	MER-011CN/112917-144	7452
23483	7590	01/16/2004	EXAMINER	
HALE AND DORR, LLP 60 STATE STREET BOSTON, MA 02109			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 01/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,072

Applicant(s)

STEINMAN ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003 and 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-6 and 10-12 are being acted upon.
2. In view of Applicant's amendment and remarks, filed 10/06/03 and 10/30/03, the previous rejection under the second paragraph of 35 U.S.C. 112 regarding the recitation of cells that "express characteristics of DCs" has been withdrawn.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-6 and 10-12 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) The term "pluripotential cells" is vague and indefinite as the term is not defined in the specification and just one example of "pluripotential cells" (PBMCs) are disclosed. It is unclear whether the terms are meant to be interchangeable or whether other types of "pluripotential cells" are encompassed by the claims, for the reasons of record as set forth in Paper No. 7, mailed 4/02/03.

Applicant's arguments, filed 10/06/03, have been fully considered but they are not persuasive. Applicant argues that the cells are defined at page 14, lines 16- 24 and at page 22, lines 18-19. Additionally, Applicant argues that "Indeed, Webster's New Collegiate Dictionary (G. & C. Merriam Co., 1981) defines "pluripotent" as "not fixed as to developmental potentialities: having developmental plasticity" (p. 878; p. 878 and cover pages attached herewith as Appendix C). Thus, it is Applicants' position that the immature dendritic cells, because they are not fixed as to developmental potentialities, are, in fact, pluripotential cells."

Applicant is advised that no definition of "pluripotential cells" has been found at pages 14 or 22. i.e., the disclosure that, "Surprisingly, we have determined that unless they are exposed to a dendritic cell maturation factor, removal of the cytokines from contact with the cells causes the cells to revert back to a pluripotential cell having characteristics similar to macrophages.", is not an adequate definition. Regarding the dictionary definition, it remains the Examiner's position that defining "pluripotential cells" as cells that are developmentally

"non fixed" or "plastic" fails to establish the metes and bounds of the claimed invention.

Applicant argues that "immature dendritic cells are also pluripotential cells."

While Applicant's argument may be true, it fails to define the genus encompassed by "pluripotential cells".

Applicant argues "As this objection applies specifically to claim 2, Applicants respectfully direct attention to the specification at page 15, lines 5-10. There, the specification states, "The pluripotent cells. . .are present in blood as PBMCs. . .the pluripotential cells may also be obtained from any tissue in which they reside, including bone marrow and spleen tissues."

Applicant is advised that a source of pluripotent cells does not comprise an adequate definition of pluripotent cells.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-6 and 10-12 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent No. 5,994,126, for the reasons of record as set forth in Paper No. 7, mailed 4/02/03.

Applicant's arguments, filed 10/06/03, have been fully considered but they are not persuasive. Applicant argues that "Applicants have overcome this ground for rejection with the present amendment to claim 1. The dendritic cells produced by the

claimed method are characterized in that they have increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression relative to the expression of these cell markers in pluripotential cells. As the '126 patent fails to teach the production of a dendritic cell having any one of these characteristics, it cannot anticipate the present claims."

It is the Examiner's position that Applicant has merely further characterized the cells produced by the method taught by the reference. Further characterization of a known method does not render said method patentably distinct.

7. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Romani et al. (1994), for the reasons of record as set forth in Paper No. 7, mailed 4/02/03.

Applicant has again argued that "Applicants have overcome this ground for rejection with the present amendment to claim 1.

Applicant is again advised that it is the Examiner's position that Applicant has merely further characterized the cells produced by the method taught by the reference. Further characterization of a known method does not render said method patentably distinct.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-6 and 10-12 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Specifically, there is insufficient written description to show that Applicant was in possession of a factor in which to culture pluripotential cells which would cause them to express characteristics of DCs, for the reasons of record as set forth in Paper No. 7, mailed 4/02/03.

Applicant's arguments, filed 10/06/03, have been fully considered but they are not persuasive. Applicant argues that "it is the Applicants' position that the precise identity of the factor is irrelevant. Rather, what is relevant is that if the ordinarily skilled artisan cultures pluripotent cells in the presence of a factor in accordance with the method described in the specification, he will obtain mature dendritic cells, as characterized by their increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression."

It is the Examiner's position that the identity of the factor, said factor being critical to the method of the instant claims, is indeed relevant.

Applicant argues that "Applicants' specification has provided two sources for the factor, namely conditioned medium and fixed *Staphylococcus aureus* (SACS) (see, e.g., page 47, line 14 through page 54, line 25)."

It is the Examiner's position that a source of said factor is not an adequate written description of said factor.

10. The following are new grounds of rejection necessitated by Applicant's amendment.

11. Claims 1-6 and 10-12 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method ... comprising ... decreased CD115 expression and decreased CD32 expression relative to the pluripotent cells.

Applicant indicates that support for the new limitations can be found at page 27, lines 18-22.

Page 27 discloses only loss of CD115 and CD32 expression and no comparison to pluripotent cells.

12. No claim is allowed.


13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


12/29/03
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER